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No. ———

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

CSX TRANSPORTATION, INC.,
Petitioner,

v.

KENNETH MCDANIEL,
Respondent.

Petition for a Writ of Certiorari to the Supreme Court of the State of Tennessee

---

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether, in a case arising under the Federal Employers' Liability Act, the Tennessee Supreme Court erred by applying Tennessee Rules of Evidence, rather than the federal rule embodied in this Court's decision in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, to the question of the admissibility of scientific expert testimony where such evidence is outcome-determinative.

LIST OF PARTIES AND RULE 29.1 DISCLOSURE STATEMENT

The only parties to this proceeding are CSX Transportation, Inc. and Kenneth McDaniel.

Pursuant to Rule 29.1 of the Rules of this Court, petitioner CSX Transportation, Inc. states that CSX Corporation is its parent company. CSX Transportation, Inc. further states that the following are its non-wholly owned subsidiaries:

Allegheny and Western Railway Company
The Baltimore and Cumberland Valley Rail Road Extension Company
The Central Railroad Company of South Carolina
The Cincinnati Inter-Terminal Railroad Company
The Cleveland Terminal & Valley Railroad Company
Dayton and Michigan Railroad Company
The Home Avenue Railroad Company

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Petition for a Writ of Certiorari to the Supreme Court of the State of Tennessee

---

PETITION FOR A WRIT OF CERTIORARI

CSX Transportation, Inc. hereby petitions for a writ of certiorari to review the judgment of the Supreme Court of the State of Tennessee in this case.

OPINIONS BELOW

The opinion of the Tennessee Supreme Court is reported at 955 S.W.2d 257 (Tenn. 1997) and is included in the Appendix at 1a-19a. The order of the Tennessee Supreme Court denying rehearing is not reported and is included in the Appendix at 51a. The opinion of the Second Circuit Court for Davidson County is not reported and is included in the Appendix at 22a-49a.

JURISDICTION

The initial decision of the Tennessee Supreme Court was entered on September 29, 1997. CSX Transportation, Inc. timely petitioned for rehearing. The Tennessee

Supreme Court denied the petition on December 8, 1997. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Federal Employers' Liability Act provides, in pertinent part:

> Every common carrier by railroad while engaging in commerce between any of the several States or Territories . . . shall be liable in damages to any person suffering injury while he is employed by such carrier in such commerce . . . for such injury or death resulting in whole or in part from the negligence of any of the officers, agents, or employees of such carrier, or by reason of any defect or insufficiency, due to its negligence, in its cars, engines, appliances, . . . or other equipment.

45 U.S.C. § 51.

Rule 702 of the Federal Rules of Evidence provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

STATEMENT

A. Factual Background

The decision below governs 84 cases filed against petitioner CSX Transportation, Inc. ("CSXT") in the Circuit Court for Davidson County by employees alleging that chronic low-level exposure to solvents in the CSXT mechanical shops at the Radnor Yard in Nashville, Tennessee caused permanent damage to the railroad employees' cognitive abilities. Respondent and the other 83 plaintiffs were all employees of CSXT who worked in the shop,

which is a locomotive repair facility at which everything from minor servicing to complete locomotive overhaul is performed. All 84 individual lawsuits were brought pursuant to the Federal Employers' Liability Act (the "FELA"), 45 U.S.C. § 51, *et seq.*, and were consolidated.

Respondents allege that each employee working in the shop might use between three and 30 gallons of solvents a day, and that this exposure caused dizziness, nausea and light-headedness. Sometime during the late 1980s and early 1990s, several employees allegedly began experiencing cognitive difficulties including memory loss, concentration difficulties, and depression. Respondents allege that these problems are the result of chronic low-level exposure to various solvents used in the shops, and sued CSXT to recover for their purported injuries.

The underlying litigation concerns four particular organic solvents: trichloroethane ("TCA"), trichloroethylene ("TCE"), perchloroethylene ("PERC"), and mineral spirits (collectively, "the solvents"). These solvents belong to a family of organic solvents known as chlorinated hydrocarbons. The utility of these solvents lies in their ability to dissolve grease. App. 4a. For the past 30 years, CSXT has used the solvents for degreasing operations in the shops.

One of the basic tenets of toxicology is that any chemical is toxic if the dose is high enough. Conversely, every chemical is safe if the dose is low enough. The effects of acute exposure to solvents, short of unconsciousness, include dizziness, dysphoria and disorientation. App. 4a. It is well established, and all the experts in this case agree, that these effects are reversible upon termination of the exposure. Each expert witness in this case testified that there are safe levels of these solvents that can be inhaled and tolerated with no permanent adverse health effects. All experts also agree that reversible, short-term dizziness and disorientation can occur upon acute exposure to high concentrations of these solvents.

"Toxic encephalopathy" is a term used to describe a poorly defined genre of brain damage. There is no objective diagnostic tool, such as an MRI, a CT Scan or an EEG, that respondents' experts can rely upon to support their diagnosis of toxic encephalopathy. App. 4a. Moreover, there is no objective symptom that is patently indicative of toxic encephalopathy upon which a definitive diagnosis may be based.

The central underlying issue in these cases is whether there is a causal link between chronic low-level solvent exposure and brain damage. In order to establish such a causal link, there must be a "biologically plausible mechanism" that explains how a person is, in fact, damaged by low-level exposure. Biologically plausible mechanisms are crucial to a scientific determination of the cause of a particular disease. Toxicological principles and evidence, in turn, are essential to the issue of whether chronic low-level solvent exposure causes brain damage.

As an alternative to proof that a biologically plausible mechanism or causal link exists, or that toxicological principles and evidence support the claim, a plaintiff is required to identify epidemiological evidence [1] that would confirm the existence of causation between solvents and central nervous system damage. These epidemiological studies must establish that there is a statistically significant relative risk that low-dose exposure causes brain damage.

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[1] Epidemiological studies examine the pattern of disease in human populations and attempt to determine whether there is an *association* between a disease and an agent suspected of causing the disease. But an "[a]ssociation is not *causation*. An association identified in an epidemiological study may or may not be causal." Federal Judicial Center, *Reference Manual on Scientific Evidence* 126 (1994). Thus, the reliability and statistical significance of the conclusions reached in these epidemiological studies should be carefully considered before a court admits such studies into evidence. *See Daubert* v. *Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993) (Rule 702 requires a "valid scientific connection to the pertinent inquiry as a precondition to admissibility").

More specifically, consistent epidemiological studies must establish that solvent exposure causes permanent central nervous system damage, with a relative risk at a sufficient level of probability to satisfy evidentiary standards, in order to make out a claim for recovery under the FELA.

B. Proceedings Below

CSXT moved for a pretrial hearing to determine whether the expert testimony expected to be offered by respondents was admissible. The circuit court held the requested hearing on August 28-31, 1995. At the hearing, several of the parties' experts testified, with the exception of Dr. Linz, one of respondents' experts, whose testimony was presented in the form of a deposition transcript. Respondents' experts based their opinions on epidemiological studies they claimed established the causation between exposure to solvents and brain damage. CSXT contended that the epidemiological studies relied upon by respondents' experts did not consistently establish a causal connection with a relative risk ratio that showed a statistically significant degree of reliability.

The circuit court issued its decision on October 2, 1995, stating that "th[e] case [regarding the admissibility of expert testimony] is one that comes under Tenn. R. Civ. P., Rule 104, 703 and 704." App. 25a. While discussing generally the federal rules and federal jurisprudence governing the admission of expert testimony, the court failed to discern the significance of the fact that this case arises under a federal statute, the FELA, and that, as such, matters affecting rights and liabilities are governed by federal law. App. 34a-46a. In addition, the circuit court failed to appreciate the impact its decision, relying upon Tennessee law, to admit expert causation testimony, which is outcome-determinative, would have on the uniformity of FELA law. Thus, without considering the larger ramifications, the court concluded that each of respondents' experts offered opinions that would be admissible at trial under Tennessee law. App. 34a-43a.

The Tennessee Supreme Court affirmed the circuit court's decision on September 27, 1997. In so doing, the Tennessee Supreme Court also ignored the fact that this case arises under the FELA, which was designed to provide a *uniform* system for railroad employees to recover for on-the-job injuries. Instead, the court found that the outcome-determinative question of the admissibility of expert causation testimony was governed by Tennessee law, which is different from the federal rule and different from many other states' rules. App. 13a. In addition, the Tennessee Supreme Court disregarded the reliability standard employed by many federal courts in assessing scientific evidence, wherein a relative risk of 2.0 or greater must be established, and concluded that such a factor was "relevant" but not required. App. 14a-15a. With those parameters set, the Tennessee Supreme Court concluded that the trial court properly admitted respondents' expert testimony. CSXT petitioned for rehearing, but the petition was denied on December 8, 1997.

REASONS FOR GRANTING THE PETITION

The decision of the Tennessee Supreme Court raises a recurring and fundamental question with respect to the standard for determining the admissibility of expert testimony in FELA cases: whether application of state evidentiary rules regarding the admissibility of expert causation testimony thwarts the FELA's purpose of maintaining a uniform national system for the recovery of damages due to injuries suffered by railroad employees while on the job, and enhances the likelihood that a litigant will engage in forum shopping in order to find a venue in which its expert testimony is most likely to be admitted. Given the centrality of the causation issue in these cases, the question of which law to apply will almost always be outcome determinative, which makes resolution of this issue vital to the proper administration of justice under the FELA.

In Tennessee alone there are over 80 cases pending that pertain to the alleged effects of solvent exposure on the

central nervous system. In each of these cases, and in the countless other cases nationwide, the admissibility of expert testimony has been and will have to be assessed. If decisions like the Tennessee Supreme Court ruling are permitted to stand, decisions in FELA cases will no longer be uniform, as state courts will feel free to admit crucial scientific evidence that the rules of evidence governing the very same case, if brought in a federal district court, would bar.

A. The Tennessee court's failure to consider the impact its decision would have on the uniformity of FELA law conflicts with this Court's precedents. The FELA was intended to replace the "patchwork of state legislation with a nationwide uniform system" of rules concerning the compensation of railroad employees for on-the-job injuries. *South Buffalo Ry. Co.* v. *Ahern*, 344 U.S. 367, 371 (1953). "This Court has long recognized that the FELA 'has a uniform operation, and neither is nor can be deflected therefrom by local statutes.'" *Burnett* v. *New York Cent. R.R. Co.*, 380 U.S. 424, 433 (1965) (quoting *Panama R.R. Co.* v. *Johnson*, 264 U.S. 375, 392 (1924)). Thus, in reversing a state court decision that applied a state procedural rule that directly affected substantive rights in a FELA case, this Court held that "only if federal law controls can the federal Act be given that uniform application throughout the country essential to effectuate its purposes." *Dice* v. *Akron, Canton & Youngstown R.R. Co.*, 342 U.S. 359, 361 (1952) (state laws are not controlling in determining what the incidents of the FELA right shall be). Therefore, the Court has also recognized that "[o]nly by a uniform federal rule as to the necessary amount of evidence may litigants under the [FELA] receive similar treatment in all states." *Brady* v. *Southern Ry. Co.*, 320 U.S. 476, 479 (1943) (citations omitted). The Tennessee Supreme Court, however, failed to heed this command.

B. The FELA was intended to preempt state law as to matters affecting the financial responsibility of the rail-

roads for injuries to their employees. Through the Supremacy Clause of the Constitution, this Court maintains the FELA's authority in state courts. There has, as a result, developed a "FELA jurisprudence" that is binding upon state courts deciding FELA cases.

In all jurisdictions, to state a cause of action under the FELA, a plaintiff must show that: (1) he was injured; (2) the railroad was negligent; and (3) the railroad's negligence caused, in whole or in part, plaintiff's alleged injuries. 45 U.S.C. § 51. In cases such as this one, proof of causation consists almost exclusively of medical and scientific evidence. If incompetent expert testimony as to causation is admitted, a railroad is denied its substantive entitlement to judgment as a matter of law because evidence insufficient for the court to allow the question to be presented to the jury under the FELA will be relied upon. That is, without evidence of causation, a case is insufficient as a matter of law and, thus, cannot reach the jury. Therefore, admission of expert evidence is outcome determinative in FELA cases and, thus, should be determined by the controlling uniform federal standard, regardless of whether the case is brought in state or federal court.

This proof of causation, as required by the FELA, is "too substantial a part" of the rights and liabilities under the Act to "permit it to be classified as a mere 'local rule of procedure.' " See *Monessen Southwestern Ry. Co.* v. *Morgan*, 486 U.S. 330, 336 (1988) (discussing availability of prejudgment interest), quoting *Dice* v. *Akron, Canton & Youngstown R.R. Co.*, 342 U.S. 359, 363 (1952) (discussing state rule that allowed judge rather than jury to resolve factual question as to whether release had been fraudulently obtained). Just as the proper measure of damages is inseparably connected to the right of action, and, thus, is a substantive issue governed by federal law, *Monessen*, 486 U.S. at 336, so, too, is expert causation testimony inseparably connected with the right of action under the FELA where, without such evidence, a plaintiff's case would be insufficient as a matter of law.

See *Chesapeake & Ohio Ry. Co.* v. *Kuhn*, 284 U.S. 44, 46-47 (1931) (rights and obligations depend upon the FELA and applicable principles of common law as interpreted and applied in federal courts).

This Court has recognized that "[a]s long as the question involves a mere matter of procedure as to the *time when* and the *order in which* evidence should be submitted the state court can . . . follow their own practice even in the trial of suits arising under the" FELA. *Central Vt. Ry. Co.* v. *White*, 238 U.S. 507, 511-12 (1915) (emphasis added). The issue here cannot be characterized as involving "when" and "in what order" evidence should be submitted. In the case at bar and the numerous others like it, the question of admissibility goes directly to whether a plaintiff has sufficient evidence to prove causation so that the issue is suitable to be presented to a jury. Given the substantive nature of the inquiry, federal law should control the admissibility of expert evidence on causation in all fora in which FELA claims are heard.

The Court has not addressed the precise issue raised by this petition. As a result, there are conflicting decisions in various state courts as to whether the *Daubert* decision, interpreting Federal Rule of Evidence 702, is the standard to be applied in determining the admissibility of expert evidence in all courts, state or federal, hearing FELA cases. Coupled with the unusually broad venue provision of the FELA, these inconsistent decisions provide railroad employees with a strong incentive to forum shop. Moreover, the problem is not simply that litigants in state courts face a different standard than litigants in federal courts; the problem is compounded by the fact that the 50 states each have their own rules and their own interpretations of those rules. The result is that two similarly situated railroad employees bringing actions in two different states' courts will obtain strikingly dissimilar results simply because of the standard each court chooses to apply to the question of the admissibility of expert testimony. Such disparity flies in the face of this Court's hold-

ings extolling the virtues of uniformity in FELA cases, as well as of Congress' purpose in enacting the FELA. The outcome of the litigation in state court "should be substantially the same, so far as legal rules determine the outcome of a litigation, as it would be if tried" in a federal court. See *Guaranty Trust Co.* v. *York*, 326 U.S. 99, 109-10 (1945) (discussing intent of *Erie Railroad* decision to insure outcome in federal courts hearing cases based on diversity is same as it would be in state court).

State court FELA decisions are not reaching the same outcome as federal courts, however, and are not even reaching the same outcome across state lines. For example, in *Berry* v. *CSX Transportation, Inc.*, No. 92-2167 CA (Fla. Cir. Ct. Apr. 28, 1995), a case also involving the alleged harm caused by exposure to solvents, the court noted this Court's decision in *Daubert*, but stated that the Florida Supreme Court had rejected the *Daubert* standard and had chosen to retain the *Frye* rule. *Berry*, slip op. at 4. Applying the *Frye* standard, the Florida trial court excluded the plaintiff's proposed expert testimony on the grounds that it was not generally accepted in the particular field and that the research on the subject was not consistent. *Id.*, slip op. at 15. On appeal, the District Court of Appeal determined, also using the *Frye* standard, that the evidence should be admitted. *Berry* v. *CSX Transp., Inc.*, Nos. 95-3131, 95-3618, 1998 WL 85601 (Fla. Dist. Ct. App. Mar. 3, 1998). Neither Florida court considered the impact that using its own rules of admissibility would have on the nationwide uniformity of FELA decisions.

In Alabama, the State supreme court has indicated that it believes it should "defer to federal law, whether it be substantive or procedural, in enforcing" the FELA. See *Illinois Cent. Gulf R.R. Co.* v. *Price*, 539 So.2d 202, 206 (Ala. 1988). Under the *Price* rule, a litigant in Alabama will find the admissibility of expert testimony in a FELA case governed by *Daubert*.

Unlike either Florida or Alabama, Tennessee imposes on its FELA litigants the Tennessee Rules of Evidence governing the admission of expert testimony. In the case at bar, the Tennessee trial court admitted expert testimony using its state standard, App. 34a-43a, whereas the *Berry* court in Florida excluded similar evidence using a different standard of admissibility. Only by addressing the issue now can the Court insure the uniformity of FELA jurisprudence that is essential to effectuate its purposes.

C. The federal rule requires that scientific evidence be sufficiently reliable in order to be admissible. *Daubert*, 509 U.S. at 590, 597 (trial judge must insure that scientific evidence or testimony is not only relevant but reliable). To establish reliability, federal courts have imposed upon the party presenting the expert the duty of showing that the "expert's findings are based on sound science, and this will require some objective, independent validation of the expert's methodology." *Daubert* v. *Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995) (*Daubert II*); see *General Elec. Co.* v. *Joiner*, 118 S. Ct. 512, 517-19 (1997) (court must determine whether experts' opinions are sufficiently supported by scientific studies; where study does not show statistically significant increase in disease, not abuse of discretion to exclude it); *Claar* v. *Burlington N.R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994) (court must determine whether experts arrived at conclusions using "scientific methods and procedures," and that conclusions were not "mere subjective beliefs or unsupported speculation"); *Summers* v. *Missouri Pac. R.R. Sys.*, 897 F. Supp. 533, 542 (E.D. Okla. 1995) (court excluded expert testimony because plaintiff failed to demonstrate "valid scientific connection to the pertinent inquiry" as precondition to admissibility, and thus did not show sufficient scientific probability) (quoting *Daubert*, 509 U.S. at 592), *aff'd*, 132 F.3d 599 (10th Cir. 1997).

In these solvent cases, objective, independent validation of expert witnesses' opinions means that the experts' opinions must be validated by epidemiological studies (see

p. 4, *supra*) that establish a statistically significant relative risk that low-dose solvent exposure causes brain damage. As federal and state courts have required, the epidemiological studies must establish that solvent exposure causes brain damage with a relative risk of 2.0 or greater. *E.g., Daubert II* at 1321; *DeLuca* v. *Merrell Dow Pharm., Inc.*, 911 F.2d 941, 958 (3d Cir. 1990) (requiring expert to show that epidemiological data relied upon had relative risk exceeding 2.0), *aff'd*, 6 F.3d 778 (3d Cir. 1993); *In re "Agent Orange" Prod. Liab. Litig.*, 597 F. Supp. 740, 785 (E.D.N.Y. 1984) (two-fold increase in incidence of disease attributable to exposure is required if epidemiological studies alone are relied upon), *aff'd*, 818 F.2d 145 (2d Cir. 1987); *Merrell Dow Pharm., Inc.* v. *Havner*, 953 S.W.2d 706, 718 (Tex. 1997) ("requirement of more than a doubling of the risk strikes a balance between the needs of our legal system and the limits of science"). In addition, the *Reference Manual on Scientific Evidence*, relied upon by many federal courts, states that the "threshold for concluding that an agent was more likely the cause of a disease than not is a relative risk greater than 2.0." Federal Judicial Center, *Reference Manual on Scientific Evidence* 168 (1994). A relative risk greater than 2.0 means that the disease more likely than not was caused by the event. If the relative risk is below 2.0, it is more likely than not that the disease was caused by something else.

The Tennessee Supreme Court, however, disregarded this reliability test, stating that it was "relevant" but rejecting "the contention that it should be adopted as [a] matter of law." App. 15a. Since the evidence offered by respondents did not meet this relative risk threshold, the Tennessee Supreme Court's affirmance of the admission of scientific evidence that was, thus, unreliable and that would have been excluded by a federal court was error. Moreover, without clear guidance from this Court that reliability of scientific evidence must be established by a relative risk of 2.0 or greater, FELA decisions will be

inconsistent and unpredictable. Such disuniformity is contrary to the purpose behind the FELA and to this Court's jurisprudence.

* * * *

In sum, the decision of the court below conflicts with this Court's precedents, and with the purpose for which the FELA was enacted to determine on a uniform basis the issue of liability of railroads for work-place injuries. Only this Court can prevent individual States from using varying standards for the admissibility of expert causation testimony when a federal rule should govern this vital, outcome-determinative consideration. Accordingly, the Court should review this case in order to prevent plaintiffs from forum shopping to find the venue in which their expert evidence will be admissible, thereby avoiding judgment against them as a matter of law.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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March 9, 1998

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APPENDICES

APPENDIX A

IN THE SUPREME COURT OF TENNESSEE
AT NASHVILLE

Filed: September 29, 1997

Davidson Circuit
Hon. Marietta M. Shipley, Judge
No. 01-S-01-9605-CV-00095

KENNETH MCDANIEL,
Plaintiff-Appellee,

VS.

CSX TRANSPORTATION, INC.,
Defendant-Appellant.

OPINION

AFFIRMED. ANDERSON, C. J.

We granted this interlocutory appeal to clarify the standards for the admissibility of scientific evidence under Tennessee Rules of Evidence 702 and 703.

The trial court, after a Tenn. R. Evid. 104 pretrial evidentiary hearing, admitted into evidence the testimony of plaintiffs' experts who relied on epidemiological studies to prove that exposure to organic solvents caused a form of brain damage known as toxic encephalopathy. The trial court found that this scientific evidence would substantially assist the trier of fact and was reliable and trustworthy.

The Court of Appeals denied an interlocutory appeal. We, however, granted the interlocutory appeal and conclude that Tennessee Rules of Evidence 702 and 703 impose a duty upon trial courts to determine whether scientific evidence will substantially aid the trier of fact and whether the underlying facts and data relied on by the expert witness indicate a lack of trustworthiness. The trial court must further determine whether the reasoning or methodology underlying the scientific evidence is sufficiently valid and reliable, and whether it can properly be applied to the facts at issue.

In making this determination, the trial court should focus on the principles and methodology underlying the science, and not on the conclusions of experts. The trial court is not required to determine that the principles and methodology employed are generally accepted by the scientific community. The court needs only to determine that the principles and methodology are scientifically valid and reliable.

When these standards are applied in this case, the scientific evidence proffered by the plaintiffs should be admitted. Accordingly, we conclude that the trial court did not abuse its discretion in denying the defendant's motion in limine which sought to exclude the plaintiffs' expert testimony.

BACKGROUND

This case involves eighty-four (84) cases filed pursuant to the Federal Employers Liability Act, 45 U.S.C. § 51, *et seq.*, by employees of the defendant CSX Transportation, Inc. ("CSXT"), a railroad operator, which were consolidated for motions and case management in the Davidson County Circuit Court. Each plaintiff alleges that he has suffered brain damage due to chronic exposure to four (4) particular organic solvents [1] while working in the CSXT mechanical shops in Nashville, Tennessee.

[1] The particular solvents at issue in this case are: trichloroethane, trichloroethylene, perchloroethylene, and mineral spirits.

The plaintiffs intend to rely upon occupational physicians to show that long-term, low dosage exposure to the solvents has caused a form of brain damage known as toxic encephalopathy, which is marked by diminished short-term memory, sleeplessness, depression and anxiety. The plaintiffs' experts rely upon epidemiological studies,[2] which they contend established the causation between long term exposure to solvents and damage to the central nervous system.

CSXT sought to exclude the plaintiffs' experts on the basis that their testimony was without sufficient scientific support. CSXT contended that the epidemiological studies relied on by the plaintiffs did not consistently establish a causal connection with a relative risk or odds ratio that shows a statistically significant degree of reliability.[3] It

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[2] Epidemiology is the "study of the distribution and determinants of health-related states and events in populations and the application of this study to control of health problems." *Reference Manual on Scientific Evidence*, Federal Judicial Center, p. 174 (1994) (hereinafter "*Reference Manual*").

There are two general types of epidemiological studies which are used to test a hypothesis: (1) cohort studies and (2) case-control studies. In a cohort study, the epidemiologist identifies a group of individuals who have been exposed to the chemical and another group of individuals who have not been exposed to the chemical. The epidemiologist chooses two groups as nearly identical as possible except for exposure to the chemical. The incidence rates of disease of the exposed and non-exposed groups over a period of time is then observed. A case-control study involves persons who either have the disease (cases) or do not have the disease (controls). The cases and controls are matched for comparison. A determination is made as to whether the individuals in the case and control groups were exposed to the chemical.

[3] After collecting the data either using a cohort or case-control study, epidemiologists typically measure risk using the concepts of "relative risk" and/or "odds ratio." Cohort studies yield a direct measure of the risk of brain damage according to the presence or absence of solvent exposure. This direct measure, known as the relative risk, is the ratio of the incidence of brain damage or "toxic encephalopathy' in the exposed group divided by the rate

concluded, therefore, that the proffered expert testimony on the issue would not "substantially assist" the trier of fact, and that the facts and data underlying the testimony shows a "lack of trustworthiness."

At a pretrial Tenn. R. Evid. 104 evidentiary hearing, several expert witnesses for the plaintiff and the defendant offered their opinions concerning the effect of long-term exposure to low doses of the organic solvents involved in this litigation. The proof indicated that the solvents belong to a family of organic solvents known as chlorinated hydrocarbons, while mineral spirits are generally distilled from petroleum products. The industrial utility of the solvents lies in their ability to dissolve grease.

The experts agreed that there is no objective diagnostic tool, (such as an MRI, CT Scan, or X-Ray), that will support a diagnosis of toxic encephalopathy, and that no biological mechanism has been identified that demonstrates how exposure to the solvents causes the damage. Moreover, while the experts agreed that acute exposure to high concentrations of the solvents can create dizziness, disorientation, and even unconsciousness, the allegations in this case involve exposure below the level necessary to render a person unconscious.

One of the plaintiffs' experts, Dr. Edward Baker, a physician specializing in occupational medicine with two masters degrees, one in public health and another in epidemiology, testified that he has authored twenty-six articles and four textbook chapters on the subject of the effects

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in the nonexposed group. If the relative risk is 1.0, then there is no association between solvent exposure and brain damage. A relative risk of 4.0 indicates that the risk of disease in the exposed group is four times higher than the risk of disease in the unexposed group. *Reference Manual* at 148. By contrast, case-control studies utilize an odds ratio in calculating risk. An odds ratio is based on a comparison of the odds of having a disease when exposed to a suspected agent and when not exposed. *Reference Manual* at 149. Relative risk and odds ratio are generally similar in most cases.

of exposure to solvents. He began studying the effects of solvent exposure on the central nervous system while on the faculty of Harvard University's School of Public Health. He has summarized epidemiological studies conducted since 1985 and has concluded that "these cross sectional studies, viewed in the aggregate, support the view that chronic solvent exposure causes impairment of neurobehavioral function." Baker, "A Review of Recent Research on Health Effects of Human Occupational Exposure to Organic Solvents," *Journal of Occupational Medicine*, Vol. 36, No. 10 (Oct. 1994).[4] Baker testified that dose/response and degree of exposure were critical to the causation inquiry.

Another plaintiffs' expert, Dr. Douglas Linz, also a physician specializing in occupational medicine, has authored four articles on the effects of exposure to solvents and has diagnosed patients with chronic encephalopathy. Like Baker, he has performed and reviewed the epidemiological studies on the subject and has concluded that "chronic low dose exposure to solvents can cause chronic encephalopathy." Dr. Howard Frumkin, a physician with a doctorate in public health, has evaluated patients for solvent exposure, and has researched and written on the effects of exposure on the central nervous system. He testified that a sufficient degree of exposure over a sufficient amount of time can cause toxic encephalopathy, and that the diagnosis of chronic encephalopathy from low dose exposure to solvents is generally accepted throughout the United States and the world.[5]

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[4] Baker's report studied among others, Hanninen (1991 & 1979); Baker (1988); Arlien-Soberg (1979); Elofsson (1980); Hane (1977); Bleeker (1991); Bolla (1990); Parkinson (1990); Maizlsih (1985); and Spurgeon (1992).

[5] The plaintiffs' fourth expert, Dr. Michael Kelly, was the examining physician who diagnosed the plaintiffs' toxic encephalopathy. He described the "differential diagnosis" procedure he used in this regard.

In contrast, Dr. Philip Edelman testified on behalf of the defendant that although dose response is critical to any toxicology study, "most" in the medical community of toxicologists did not accept the causal connection between low dose exposure to solvents and encephalopathy. Edelman, a physician who is board certified in toxicology and occupational/environmental medicine, criticized the epidemiological studies that the plaintiffs' experts relied upon for lacking a good dose/response relationship and for failing to control for confounding factors such as age, intelligence, and the use of alcohol. Likewise, Dr. Joseph McLaughlin, a Ph.D. in epidemiology, testified that the epidemiological studies on the relation between exposure to solvents and toxic encephalopathy failed to account for significant confounding factors. Finally, Dr. Robert James, a Ph.D. in pharmacology, testified that he reviewed forty-five cross sectional studies and determined that 84 percent supported the hypothesis and 16 percent did not. He criticized the "positive" studies, however, for failing to account for the factors of age, intelligence, experience, and alcohol consumption. In James's opinion, the diagnosis of toxic encephalopathy from exposure to solvents was not generally accepted in the medical community.

After considering the testimony of the experts and analyzing the pertinent studies, the trial court concluded that the proposed evidence was "grounded in scientific theory," was "generally accepted in the occupational health community," and was trustworthy and reliable. Although denying the defendant's motion to exclude the expert testimony, the trial court recognized the need to develop a uniform and consistent body of law and granted the defendant's motion for an interlocutory appeal pursuant to Tenn. R. App. P. 9. Although the Court of Appeals denied the interlocutory appeal, we granted the appeal to clarify the standards for determining the admissibility of scientific evidence in this jurisdiction. We now affirm the trial court.

SCIENTIFIC LITERATURE

We begin our analysis by reviewing the relevant material that was submitted to the trial court and discussed by several of the experts during the evidentiary hearing. In the 1970's, researchers in certain Scandinavian countries, performing epidemiological studies using case report and cross-sectional methods,[6] reported that neuropsychiatric symptoms may be induced by long-term exposure to solvents. In 1979, the Danish physician, Arlien-Soborg, coined the phrase "chronic painters' syndrome," in a study done on seventy house painters. The report concluded that the majority of the painters who had been exposed to organic solvents, often through a period with acute intoxication symptoms, had gradually developed signs of a chronic brain syndrome. The symptoms included impaired memory, fatigue, personality change, headaches, and irritability. Arlien-Soborg, et al., "Chronic Painters' Syndrome—Chronic Toxic Encephalopathy in House Painters," *Acta. Neurol. Scand*, 60:149-156 (1979). Other authors, including plaintiffs' expert Dr. Edward Baker, have reported that the Scandinavian studies supported the hypothesis that toxic encephalopathy occurs in individuals heavily exposed to solvents over a period of

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[6] Cross-sectional studies involve selection of individuals, regardless of exposure or disease status. Subjects for such studies are chosen either at random or via probability sampling procedures, which allows for the examination of the prevalence of a disease in a representative sample of the population. McCunney, "Epidemiology and Biostatics," *A Practical Approach to Occupational and Environmental Medicine* (2nd Ed.)," at 349. Case reports are not epidemiological studies, but merely reports of individuals who have been exposed to an agent and then report symptoms associated with the disease. Case reports usually precede the institution of formal epidemiological research, although they can be important in determining whether an association exists between an agent and a disease or defect. For example, the medical community became aware of the association between the drug, Thalidomide, used by pregnant women as a sedative and birth defects in their children as a result of case reports.

months to years. *See* Baker, et al., "The Neurotoxicity of Industrial Solvents: A Review of the Literature," *Am. J. of Indus. Med.*, 8:207-217 (1985).[7]

As the defendant contends, the Scandinavian studies have been criticized for failing to prove that the painters' symptoms were related to their occupational exposure to organic solvents and for the disappearance of evidence of impairment in twenty re-examined workers. *See* Errebo-Knudsen and Olsen, "Organic Solvents and Presenile Dementia (The Painters' Syndrome): A Critical Review of the Danish Literature," *The Sci. of the Total Env't*, 48:45-67 (1986); Gade et al., "Chronic Painter's Syndrome. A Reanalysis of Psychological Test Data in a Group of Diagnosed Cases," *Acta Neurol. Scand.*, 77:293-306 (1988).

Some studies have likewise questioned the Scandinavian studies. As one report indicates:

> Studies outside Scandinavia, mainly cross-sectional clinical studies, have not supplied convincing evidence to support the hypothesis of solvent exposure causing irreversible brain damage. . . . The reason for this discrepancy might lie in differences of study design, incomparable study populations, insufficient adjustment for confounding factors, and, perhaps most importantly, differences in disease classification.

Rasmussen et al., "Solvent-Induced Chronic Toxic Encephalopathy," *Am. J. Of Indust. Med.*, 23:779-792 (1993); *see also* Williamson et al., "A Prospective Cohort Study of the Chronic Effects of Solvent Exposure," *Environmental Res.*, 62:256-271 (1993) ("cross sectional studies suffer from problems of possible confounding by a range of unknown factors and also usually from poor estimates

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[7] Other studies referenced by the parties supporting the theory include Axleson, et al., 1976; Hanninen, et al., 1976; Hane, et al., 1977; Harkonen, et al., 1977; Knave, et al., 1978; Mikkelson, 1980; and Gregersen, et al., 1987, among others.

of exposure."). Moreover, other studies have reached opposite results. *See, e.g.,* Spurgeon, et al., "Investigation of Dose Related Neurobehavioral Effects in Paintmakers Exposed to Low Levels of Solvents," *Occupational & Environmental Medicine,* 51:626-630 (1994) (cross sectional study of 110 paintmakers resulted in view that "long term exposure at or below current compliance levels does not result in damage to the central nervous system.").

Despite the criticisms, textbooks and review articles recognize the diagnosis of toxic encephalopathy. For example, in the chapter entitled "Organic Solvents and Related Compounds" of the *Textbook of Clinical Occupational and Environmental Medicine,* the authors state that "there is currently sufficient support for the association of high long-term solvent exposure with long-lasting psychoorganic symptoms to consider this a clinical reality." Rosenstock and Cullen, at p. 773 (1994).

International and national governmental health organizations also have recognized the syndrome. For example, at the World Health Organization and Nordic Council of Ministers meeting in Copenhagen, Denmark, in June 1985, it was stated that "[c]linical, epidemiological and experimental data indicate that long-term occupational exposure to organic solvents may cause adverse effects in the central and the peripheral nervous systems." It was recommended that further "clinical, experimental and epidemiological studies should be undertaken to gain further insight into the reversibility of the neurotoxic effects induced by the solvents, their health significance and the dose-effect, dose-response relationships." *Id.* at pp. 32-33.

The National Institute for Occupational Safety and Health ("NIOSH") "Current Intelligence Bulletin 48," issued on March 31, 1989, makes similar observations and recommends that producers and users inform their customers, that trade associations and unions warn their workers, and that protective equipment and worker education be used to reduce worker exposure—at least to

concentrations specified in exposure lists of OSHA and other organizations. *Id.* at iii-iv.

Accordingly, as the trial court found, numerous epidemiological studies support the diagnosis of toxic encephalopathy from exposure to solvents. While other reports have criticized the epidemiological studies, the diagnosis is recognized in textbooks and journals, as well as by national and world health organizations. It is with this background that we now turn to the legal principles governing the admissibility of scientific evidence.

SCIENTIFIC EVIDENCE

Nearly 75 years ago, the test for determining the admissibility of scientific evidence was established in the landmark federal case of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). In *Frye*, which involved a polygraph examination, or lie detector, the court said that scientific evidence will be admissible only if it has "gained general acceptance in the particular field in which it belongs." *Id.* at 1014. This rule, although followed by the vast majority of federal and state jurisdictions, including Tennessee, was often criticized for being too restrictive of relevant evidence, particularly new or "cutting edge" scientific theory, and too vague for uniform application. *See e.g., Symposium of Science and the Rules of Evidence*, 99 F.R.D. 188 (1983) (and extensive authority discussed therein).

The federal courts embarked on a new and less restrictive course with the decision recently in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), by the U.S. Supreme Court where the Court reversed the 9th Circuit and determined that the "general acceptance" test set forth in *Frye* was superseded by Fed. R. Evid. 702:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as

> an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

According to the Court, Rule 702 requires a determination as to "whether the expert is proposing to testify regarding scientific knowledge that will assist the trier of fact to understand or determine a fact in issue." *Daubert*, 509 U.S. at 592, 113 S.Ct. at 2796. This determination requires the trial court to consider "whether the reasoning or methodology underlying the testimony is scientifically valid and of whether the reasoning or methodology properly can be applied to the facts in issue." *Id.* In analyzing scientific validity or reliability, the trial court must focus on "principles and methodology, and not on the conclusions they generate." *Id.*, 509 U.S. at 595, 113 S.Ct. at 2797.

A partial list of factors the Supreme Court deemed relevant to the inquiry included whether the theory or technique has been tested, whether it has been subject to peer review or publication, whether there is a known or potential rate of error, and whether, as formerly required under *Frye*, it is generally accepted in the relevant scientific field. *Id.*, 509 U.S. at 593-94, 113 S.Ct. at 2796-2798. On remand, the Ninth Circuit Court of Appeals also considered whether the expert proposes to testify about research conducted independent of litigation or whether the expert had formulated an opinion for the express purpose of testifying. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317 (9th Cir.) ("Daubert II"), *cert. denied*, 116 S.Ct. 189, 133 L.Ed.2d 126 (1995).

Daubert's influence was felt in *Joiner v. General Electric Co.*, 78 F.3d 524, 530 (11th Cir. 1996), *cert. granted* 117 S.Ct. 1243, 137 L.Ed.2d 325 (1997). There, the trial court ruled that the plaintiff could not present expert testimony that his exposure to polychlorinated biphenyls had caused lung cancer and granted the defendant's mo-

tion for summary judgment. On appeal, the Eleventh Circuit, applying *Daubert*, emphasized:

> In analyzing the admissibility of expert testimony, it is important for trial courts to keep in mind the separate functions of judge and jury, and the intent of *Daubert* to loosen the strictures of *Frye* and make it easier to present legitimate conflicting views of experts for the jury's consideration.

The court stressed the trial court's role was a narrow one:

> This gatekeeping role is simply to guard the jury from considering as proof pure speculation presented in the guise of legitimate scientifically-based expert opinion. It is not intended to turn judges into jurors or surrogate scientists. *Thus, the gatekeeping responsibility of the trial courts is not to weigh or choose between conflicting scientific opinions, or to analyze and study the science in question in order to reach its own scientific conclusions from the material in the field. Rather, it is to assure that expert's opinions are based on relevant scientific methods, processes, and data, and not on mere speculation and that they apply to the facts in issue.*

Id. at 530 (emphasis added). After applying the *Daubert* inquiry and analyzing the principles and methodology underlying the plaintiff's scientific evidence, the Eleventh Circuit Court of Appeals held that the trial court erred in excluding the evidence.

Although the federal courts have decided a new and less restrictive direction was appropriate, state courts are still wrestling with the choice between *Frye* and *Daubert*. For example, in a case involving the exact same parties, issues, and experts as the present case, a Florida state circuit court, applied the *Frye* test, which was retained in that jurisdiction by the Florida Supreme Court, and concluded that the epidemiological studies were inconsistent and that the criticisms of these studies—that the plaintiffs

had failed to show the evidence was "generally accepted" in the relevant scientific community—were valid and, therefore, ruled that the evidence was inadmissible. *See Roy Lee Berry v. CSX Transportation, Inc.*, No. 92-2167 (filed April 28, 1995).

On the other hand, in a federal case involving the exact same parties, issues, and experts as the subject case, the federal district court for the Southern District of Georgia applied *Daubert*, and concluded that the evidence was admissible. The district court found that the epidemiological studies supported the plaintiff's claim that exposure can cause impairment, and found that the studies and results were scientifically valid and reliable notwithstanding the criticisms by opposing experts and reports. The court rejected the defendant's claim that the plaintiffs must show causation with a relative risk or odds ratio of 2.0 or greater. *See Bob Allen, et al. v. CSX Transportation, Inc.*, (S.D. Ga., filed Sept. 10, 1996).

THE TENNESSEE STANDARD

After examining the basic legal principles governing the admissibility of scientific evidence and the change in direction by the federal courts, we turn to Tennessee to clarify our standard of admissibility.

In general, questions regarding the admissibility, qualifications, relevancy and competency of expert testimony are left to the discretion of the trial court. *State v. Ballard*, 855 S.W.2d 557, 562 (Tenn. 1993). The trial court's ruling in this regard may only be overturned if the discretion is arbitrarily exercised or abused. *Id.* The specific rules of evidence that govern the issue of admissibility of scientific proof in Tennessee are Tenn. R. Evid. 702 and 703.[8] The former provides:

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[8] Of course, scientific evidence also must be relevant before it is admissible. As stated in Tenn. R. Evid. Rule 401, "[r]elevant evidence means evidence having any tendency to make the existence

> If scientific, technical, or other specialized knowledge will substantially assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise.

And Tenn. R. Evid. 703 states:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence. The court shall disallow testimony in the form of an opinion or inference if the underlying facts or data indicate lack of trustworthiness.

The plaintiffs contend that the expert testimony in this case is reliable and that it will substantially assist the jury on the issue of causation. The defendant argues that irrespective of *Frye* or *Daubert*, there must be adherence to the strict requirements contained in the language of the rules and also a reasonable standard for proving causation. It contends that the plaintiffs' scientific evidence is unreliable and must be excluded. The defendant argues that an epidemiological study must show a relative risk of greater than 2.0, which several courts have said means that a disease more likely than not was caused by the specific agent or event. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995), *cert. denied*, 116 S.Ct. 189, 133 L.Ed.2d 126 (1995); *Deluca v. Merrell Dow Pharmaceuticals, Inc.*, 791 F.Supp. 1042 (D.N.J. 1992), *aff'd*, 6 F.3d 778 (3rd Cir. 1993).

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of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."

As discussed herein, the factor is certainly relevant but we reject the contention that it should be adopted as matter of law.

Although the advisory comments to Rule 702 indicate that Tennessee has followed the *Frye* test in analyzing the admissibility of scientific evidence, one commentator, recognizing the similarity between Tennessee Rule 702 and Federal Rule Evid. 702, has raised the question of whether the *Frye* test of "general acceptance" should be abolished in Tennessee. N. Cohen, S. Sheppeard, and D. Paine, *Tennessee Law of Evidence*, § 401.20 at 124, n. 233. Indeed, as the trial court in this case noted, there is some evidence of a departure from the strict adherence to the *Frye* test by courts in this State.[9]

In our view, determining the standard for the admissibility of scientific evidence requires an analysis of the unique language found in Rules 702 and 703 of the Tennessee Rules of Evidence. For instance, Tenn. R. Evid. 702 requires that the scientific evidence *"substantially* assist the trier of fact," while its federal counterpart requires only that the evidence "assist the trier of fact." Fed. R. Evid. 702. This distinction indicates that the probative force of the testimony must be stronger before it is admitted in Tennessee. *See, e.g.*, Weinstein. *Rule 702 of the Federal Rules of Evidence is Sound: It Should Not Be Amended*, 138 F.R.D. 631, 636 (1991).

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[9] The trial judge identified four different standards used by Tennessee courts to determine admissibility of scientific evidence: (1) "Scientifically acceptable and accurate for its purpose." *State v. Johnson*, 717 S.W.2d 298 (Tenn. Crim. App. 1986); (2) "Four-prong threshold test involving whether the witness is an expert; whether the subject matter is proper; whether the subject matter conforms to a generally-accepted theory; and whether the probative value of the witness' testimony outweighs its prejudicial effect." *State v. Schimpf*, 782 S.W.2d 186 (Tenn. Crim. App. 1989); (3) "*Frye* or Tenn. R. Evid. 702 and 703." *State v. Harris*, 866 S.W.2d 583 (Tenn. Crim. App. 1992); and (4) "Analysis under several tests" *State v. Myers*, 1992 WL 297626 (Tenn. Crim. App. 1992).

Similarly, Tenn. R. Evid. 703 states that "[t]he court shall disallow testimony in the form of an opinion or inference if the underlying facts or data indicate lack of trustworthiness." There is no similar restriction in the federal rule, Fed. R. Evid. 703. Thus, as one writer has observed, "the additional language . . . [in the Tennessee rule] is obviously designed to encourage trial courts to take a more active role in evaluating the reasonableness of the expert's reliance upon the particular basis for his or her testimony." R. Banks, *Some Comparisons Between the New Tennessee Rules of Evidence and the Federal Rules of Evidence, Part II*, 20 Mem.S.U.L. Rev. 499, 559 (1990). In sum, even though the facts and data need not be admissible, they must be reviewed and found to be trustworthy by the trial court.

Based on the foregoing analysis, we conclude that Tennessee's adoption of Rules 702 and 703 in 1991 as part of the Rules of Evidence supersede the general acceptance test of *Frye*. In Tennessee, under the recent rules, a trial court must determine whether the evidence will substantially assist the trier of fact to determine a fact in issue and whether the facts and data underlying the evidence indicate a lack of trustworthiness. The rules together necessarily require a determination as to the scientific validity or reliability of the evidence. Simply put, unless the scientific evidence is valid, it will not substantially assist the trier of fact, nor will its underlying facts and data appear to be trustworthy, but there is no requirement in the rule that it be generally accepted.

Although we do not expressly adopt *Daubert*, the nonexclusive list of factors to determine reliability are useful in applying our Rules 702 and 703. A Tennessee trial court may consider in determining reliability: (1) whether scientific evidence has been tested and the methodology with which it has been tested; (2) whether the evidence has been subjected to peer review or publication; (3)

whether a potential rate of error is known; (4) whether, as formerly required by *Frye*, the evidence is generally accepted in the scientific community; and (5) whether the expert's research in the field has been conducted independent of litigation.

Although the trial court must analyze the science and not merely the qualifications, demeanor or conclusions of experts, the court need not weigh or choose between two legitimate but conflicting scientific views. The court instead must assure itself that the opinions are based on relevant scientific methods, processes, and data, and not upon an expert's mere speculation. *See, e.g., Joiner*, 78 F.3d at 530. The trial court should keep in mind that the preliminary question under Tenn. R. Evid. 104 is one of admissibility of the evidence. Once the evidence is admitted, it will thereafter be tested with the crucible of vigorous cross-examination and countervailing proof. After that occurs, a defendant may, of course, challenge the sufficiency of the evidence by moving for a directed verdict at the appropriate times. *See* Tenn. R. Civ. P. 50. Yet it is important to emphasize that the weight to be given to stated scientific theories, and the resolution of legitimate but competing scientific views, are matters appropriately entrusted to the trier of fact. *See Joiner*, 78 F.3d at 534-35 (Birch, J., concurring).

We recognize that the burden placed on trial courts to analyze and to screen novel scientific evidence is a significant one. No framework exists that provides for simple and practical application in every case; the complexity and diversity of potential scientific evidence is simply too vast for the application of a single test. *See Developments in the Law—Confronting the New Challenges of Scientific Evidence*, 108 Harv. L. Rev. 1481, 1513-1516 (1995). Nonetheless, the preliminary questions must be addressed by the trial court, *see*, Tenn. R. Evid. 104, and they must be addressed within the framework of rules 702 and 703.

APPLICATION OF STANDARD

The trial court correctly foresaw the trend away from *Frye* and also used the factors set forth in *Daubert* as a framework for analysis. As it observed, the scientific theory that exposure to solvents may cause toxic encephalopathy has been tested frequently over a period of 25 years. Because no precise diagnostic device or biological mechanism can isolate the causal factor, the relevant tests have been epidemiological studies. The experts in this case testified at length about the field of epidemiology and the use of cohort and case-control studies. The experts agreed that epidemiological studies have been used to test the hypothesis that exposure to solvents causes encephalopathy and that numerous studies support a causal relationship. These studies have been reviewed, reconstructed, published in leading journals in the field, and subjected to peer review. Although the "positive" studies have been criticized for failing to account for confounding factors, the diagnosis is recognized in medical textbooks and journals as well as by several national and world health organizations. We also observe that the research in this area, including that of several of the plaintiffs' experts, was conducted independently of this litigation.

Accordingly, we agree with the trial court's finding that the evidence will substantially assist the jury to understand the evidence and to determine a fact in issue. We also agree with the trial court's conclusion that the methodology and principles underlying the scientific evidence are sufficiently trustworthy and reliable to be presented to the trier of fact. The trial court is not required to determine whether it agrees with the evidence and should not substitute its view for the trier of fact. It should allow the jury to consider legitimate but conflicting views about the scientific proof. Provided the evidence is scientifically valid, criticisms of it and opposing views may be elicited on cross examination and/or

established in the defendant's case. That is the essence of the lawsuit.

CONCLUSION

We have concluded that the scientific evidence proffered by the plaintiffs satisfies the requirements of Tenn. R. Evid. 702 and 703, and that the trial court did not abuse its discretion in admitting it into evidence. The trial court's order denying the defendant's motion in limine is therefore affirmed and this case is remanded to the trial court for further proceedings. Costs of the appeal are assessed against the defendant.

/s/ E. Riley Anderson
E. RILEY ANDERSON
Chief Justice

Concur:

Drowota, Reid, Birch and Holder, JJ.

[Filed Sep. 29, 1997]

SUPREME COURT, NASHVILLE

Appeal No. 01-S-01-9605-CV-00095

Davidson Circuit
No. 93C-2215

Affirmed

KENNETH MCDANIEL,
Plaintiff/Appellee,

vs.

CSX TRANSPORTATION, INC.,
Defendant/Appellant.

JUDGMENT

This cause came on to be heard upon the record on appeal from the Davidson County Circuit Court, briefs and argument of counsel; and upon consideration thereof, this Court is of the opinion that the trial court correctly ruled that the scientific evidence proffered by the plaintiffs is admissible pursuant to Tenn. R. Evid. 702 and 703 and correctly denied the defendant's motion in limine seeking to exclude the evidence.

In accordance with the opinion filed herein, it is, therefore, ORDERED AND ADJUDGED by this Court that the judgment of the Davidson County Circuit Court is affirmed, and the case is remanded to the trial court for further proceedings.

Costs of appeal will be paid by the defendant, CSX Transportation, Inc., for which execution may issue if necessary.

APPENDIX B

[Filed May 20, 1996]

IN THE SUPREME COURT OF TENNESSEE
AT NASHVILLE

Davidson Circuit, C.A. No. 01A01-9601-CV-00022

KENNETH MCDANIEL,
Plaintiff-Appellee,

v.

CSX TRANSPORTATION, INC.,
Defendant-Appellant.

ORDER

Upon consideration of the application for permission to appeal and the entire record in the above cause, it is the decision of the Court that the application should be granted.

The Clerk is instructed to set this matter for hearing during the October 1996 session of the Court. The case is to be argued concurrently with *State v. Cora Murphy,* application granted February 20, 1996.

PER CURIAM

APPENDIX C

[Filed Oct. 3, 1995]

IN THE SECOND CIRCUIT COURT
FOR DAVIDSON COUNTY TENNESSEE

Case No. 93C-2215
All Consolidated Cases

KENNETH MCDANIEL,
Plaintiff,

vs.

CSX TRANSPORTATION, INC.,
Defendant.

MEMORANDUM OPINION

I. *History of Case and Hearing*:

Pursuant to the orders of April 27, 1994, July 15, 1994 and March 20, 1995, some 82 cases have been consolidated for discovery purposes in this court. If any future cases are filed, they will also be bound by all general orders of this court in regards to discovery, preliminary ~~evidentiary issues, and case management.~~

As these cases were pending, the court met periodically with the attorneys in pre-trial conferences. We have attempted to determine the most expeditious way to manage these cases. We discussed various methods including selecting representative cases and trying them to a conclusion as well as other methods. On May 2, 1995, the defendants filed a motion to determine the preliminary admissibility of the plaintiff's experts under Tenn. R. Evid. 104(a). After considering the matter in two pre-trial con-

ferences, the court and the parties determined that we would conduct a hearing for a total of four days to test the sufficiency of the plaintiffs' proposed experts. During the final pre-hearing conference, the court determined that each side could present no more than five experts either live or by deposition. Each side would be given approximately equal time to present direct proof and cross-examine the other's experts during the four day hearing. The parties spent the entire summer deposing and preparing the experts for the hearing on August 28-31, 1995.

II. *Status of other similar cases pending in other jurisdictions*

At that time of the filing of the defendant's motion to exclude, the court was aware that the Circuit Court in Duval County, Florida had held a similar 6-day hearing in February, 1995. Judge Michael Weatherby issued an opinion on April 28, 1995 that the plaintiffs could not present expert witnesses on this issue in that court in the case of *Roy Lee Berry, Jr. v. CSX Transportation, Inc.* File 92-02167-CA.

His conclusion was based on the *Frye* test—general acceptance in the medical community. The Supreme Court of Florida had determined after *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786 (1993) that *Frye* was still the test. The common experts in that case were Dr. Edward Baker and Dr. Michael Kelly, plaintiff's experts, and Dr. Robert James, defendant's expert. On August 23, 1995 Judge Weatherby made a similar ruling in another CSX case, *James Crisco vs. CSX*, File No. 93-2188CA, because the *Berry* case terminated with Mr. Berry's death. From the second opinion, the plaintiffs presently have an appeal pending in the Florida appellate court. There are a total of 22 cases presently pending in Jacksonville, Florida before seven judges. Two other judges, Judge Taylor and Judge Fay, have recently stayed any trials in their courts, pending the outcome of the appeal in the *Crisco* case.

Judge William Moore, Jr., of the U.S. District Court of the Southern District of Georgia has about 18 cases pending. He has scheduled a similar pre-trial evidentiary hearing on September 14, 1995 in the case of *Bobby Allen vs. CSX*, No. 594-049. Judge Warren Davis of Gwinnet County, Georgia has a 25 cases pending. He issued a decision on August 22, 1995, that he would make no rulings until the trial of the first case which is set for October 9, 1995. U.S. District Judge James Graham has at least one case pending before him, *Robert Hooper vs. CSX*, CV293-166. On March 22, 1995, he made a decision based solely upon briefs that he would make no decisions until trial.

This court is presently in communication with the U.S. District Court in Southern Georgia, so that this type of hearing does not have to be constantly repeated. Apparently Judge Moore plans to the use the transcripts in this case to make a further decision in his cases.

Outside the Southeast, there is one published case of note, *Clarr (Eggar) v. Burlington Northern R. Co.*, 29 F.3d 499 (C.A. 9 (Mont.) 1994). In this case the Ninth Circuit reviewed the granting of summary judgment by the District Court of Montana in a similar fact pattern, *Eggar vs. Burlington*, 1991 U.S. Dist., Lexis 19240, December 18, 1991. 27 employees of the railroad alleged they had medical conditions that were caused by exposure to organic solvents. The court ordered the employees to submit affidavits from physicians listing each plaintiff's specific injuries, the particular chemical that caused each injury, and the scientific basis for the physicians' conclusions. Six cases were selected as test cases. Relying on Fed.R.Evid. 104(a), 403, 702 and 703, the lower court rejected the affidavits due to the unreliability of the methodology or reasoning on a motion for summary judgment. The lower court found the affidavits to be "subjective belief and unsupported speculation." *Claar,* 29 F.3d at 502. The Ninth Circuit scrutinized the lower court's findings

in light of *Daubert*, and upheld the decision finding the physicians became familiar with the field only after litigation began; that they formed their opinions before reviewing the literature and particularly that they did not rule out alternative causes for the complaints, and finally they did not refer to their employment, school and medical records. *Eggars*, 1991 U.S. Dist. LEXIS 19240 at 29-36.

It is clear judges in various jurisdictions are carefully scrutinizing these claims based upon the law in their jurisdiction. It is important that we continue to communicate across state lines.

III. *Standard of admissibility of scientific evidence*

The decision in this case is one that comes under Tenn. R. Civ. P., Rule 104, 703 and 704. These rules were adopted in 1989, and were in effect January 1, 1990. They are identical to the Federal Rules of Evidence, except where noted in bold [brackets].

> **Rule 104** states as follows: Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination the court is not bound by the rules of evidence except those with respect to privileges.
>
> **Rule 702** states as follows: If scientific, technical, or other specialized knowledge will **[substantially]** assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise.
>
> **Rule 703** states as follows: The facts or data in a particular case upon which an expert bases an opin-

> ion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence. **[The court shall disallow testimony in the form of an opinion or inference if the underlying facts or data indicate lack of trustworthiness.]**

Federal Law

Frye Test: 1923-1993

In 1923, the District of Columbia Court of Appeals in a one page decision of *Frye v. United States,* 293 F. 1013 (App. D.C. 1923) considered the admission of a systolic blood-pressure deception test. The defendant's counsel wanted the scientist to testify to the reliability of this test and even to conduct the test in the presence of the jury. The court stated:

> Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have **gained general acceptance in the particular field in which it belongs.** [emphasis added] *Frye*, 293 F. at 1014.

The *Frye* test was generally accepted by all federal and state courts until the 1950's and 1960's, particularly following the adoption of the Federal Rules of Evidence in 1975. *Frye* has been criticized for vagueness, inconsistency, and difficulty in identifying the appropriate scientific community. Many courts started using a "relevancy" standard. *See,* Bert Black, "Evolving Legal Standards for the Admissibility of Scientific Evidence," 239 *Science* 1508, 1512 n.1 (1988).

These competing interpretations were in flux when the Bendectin cases flooded the federal courts, in the wake of the Agent Orange cases. The Sixth Circuit case of *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (C.A. 6 (KLC) (1992) is most relevant to this case, as it analyzes an emerging tort which had been considered in various jurisdictions, just prior to *Daubert*. In *Turpin*, Judge Merritt reviewed all cases which had considered the causal effect between Bendectin and birth defects. His analysis was:

> 1) Was the "validity of the reasoning process by which various competing qualified experts have reached their conclusions" proper and
>
> 2) was the evidence "sufficient to withstand the defendant's motion for summary judgment." *Turpin*, 959 F.2d at 1350.

At that point, only the D.C. Court of Appeals had found causation, where it reinstated a jury verdict. Four federal circuits held as a matter of law the plaintiffs failed to establish causation (Fifth, Ninth, First, and D.C. Circuit). *Id.*, at 1351. Four district courts had granted summary judgment, primarily on expert causation issues. Judge Merritt described it as

> "an orchestra which travels to different music halls, substituting musicians from time to time but playing essentially the same repertoire." *Id.*

The defendants presented 35 studies finding no causal connection between birth defects and Bendectin, including a study of 50,282 mothers. The rate of birth defects in the exposed population compared to those unexposed was approximately the same, i.e. no statistical significance. Similar studies with similar results were completed in other countries. The plaintiffs' counter studies were animal studies and in vitro studies. The lower court rejected the sole plaintiff's expert, Dr. Palmer's testimony as it was

pure conclusion and not based on any understandable scientific basis. The Sixth Circuit affirmed the decision.

Daubert: 1993-Present

Speculation and scholarship on the standard of review resolved with the long-awaited Supreme Court case of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786 (1993). The Supreme Court under Fed. R. Evid. 104 gave the court the role of gatekeeper in determining, pursuant to Fed. R. Evid. 702 whether the expert proposes to testify to

(1) scientific knowledge ["an inference or assertion must be derived by the scientific method"] that

(2) will assist the trier of fact to understand or determine a fact in issue." *Daubert*, 113 S.Ct. at 2796.

The four prong test is as follows:

1) Falsifiability, refutability or testability. Is this theory testable?

2) Has this theory been subjected to peer review and publication? Although not dispositive, "it is a component of 'good science' in part because it increased the likelihood that substantive flaws in methodology will be detected."

3) Is there a known or potential rate of error?

4) Is there 'general acceptance' in the relevant scientific community? Although not dispositive, it "can yet have a bearing on the inquiry." *Id.*, at 2796-7.

In short, "The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." *Id.* at 2797. The court struck a balance between abandoning the 'general acceptance' standard, citing good cross-examination and directed verdicts, and

the screening role of the judge needing resolution of disputes "finally and quickly." *Id.*, at 2798. Justice Blackmun concluded:

> . . . the Rules of Evidence—especially Rule 702—do assign to the trial judge the task of **ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand.** Pertinent evidence based on scientifically valid principles will satisfy those demands. [emphasis added] *Id.*, at 2799.

With those words, the Supreme Court remanded the case back to the Ninth Circuit.

Daubert II, Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (C.A. 9 (Cal.) (Jan. 1995), reconsidered its decision in the light of the first *Daubert* decision and added two additional factors. 5) Was the testimony developed solely for the litigation or did it arise out of independent, non-litigation related research?, i.e. Scientists work in labs. Lawyers and judges work in court. *Daubert*, 43 F.3d at 1317.

6) If the subject is too new and there is no opportunity for peer reviewed articles, has the scientist conducted research which satisfies the judge that the conclusions are valid? *Id.*, at 1318.

The court found the expert affidavits were prepared solely for the litigation as to "the effect of Bendectin on limb reduction defects." *Id.*, 1321. Secondly, there was no scientific scrutiny by peer review and publication. "It's as if there were a tacit understanding within the scientific community that what's going on here is not science at all, but litigation." *Id.* The court rejected the plaintiff's studies as they were animal and lab studies and a reanalysis of epidemiological reports with no published articles or explanations. The best the plaintiffs could do in the original case was that "Benedictin could *possibly* have caused plaintiffs' injuries. (*Daubert v.*

Merrell Dow Pharmaceuticals, Inc., 727 F. Supp. 570, 576 (S.D. Cal. 1989). Thus, the court determined that on remand, the plaintiffs could simply not correct their shortcomings and affirmed their original decision to disallow the plaintiffs' experts.

Tennessee Law

The history of expert evidence admissibility in Tennessee is confusing and convoluted. *Daubert* aside, the courts have used four different standards to determine the admissibility of scientific evidence. *See, State v. Myers,* 03C019108CR00255 WL 297626 (Tenn. Cr. App. October 22, 1992).

1) Scientifically acceptable and accurate for its purpose.

State v. Johnson, 717 S.W.2d 298 (Tenn. Cr. App. 1986) the leading case in Tennessee, is cited in the Commission notes under Rule 702 that "Tennessee law is consistent with *Frye*," although the decision itself only mentions *Frye* and then moves away from it. *State v. Johnson* was a criminal/DUI case. The sole issue was whether the trial judge erred in granting the motion to suppress the evidence of the breathalyzer test. Judge Scott reversed the trial court's suppression, confirming the Tennessee standard is ". . . scientifically acceptable and accurate for the purpose for which it is used," *Johnson*, 717 S.W.2d at 303, citing *Pruitt v. State*, 393 S.W.2d 747, 751 (Tenn. 1965), *Crawley v. State*, 413 S.W.2d 370, 373 (Tenn. 1967), and *Fortune v. State*, 277 S.W.2d 381 (Tenn. 1955).

Judge Scott acknowledged the first requirement for admission of scientific evidence was "general acceptance in the particular field in which the evidence belongs," the *Frye* standard. However, the modern trend expressed in Rule 702 of the Federal Rules of Evidence, was leading away from *Frye*. Judge Scott concluded, "There is no requirement in the rule that the scientific principles be generally accepted in the scientific community." *Id.*

Instead he implemented a three factor test established in *U.S. v. Downing*, 753 F.2d 1224, 1237 (3d Cir. 1985) to consider admission of "novel scientific evidence." *Id.* The 3rd Circuit court apparently held that the *Frye* test is at odds with the spirit of Fed. R. Evid. 702, even if the language is similar. *Id.* The three factors listed are:

> (1) the soundness and reliability of the process or technique used in generating the evidence;
>
> (2) the possibility that admitting the evidence would overwhelm, confuse or mislead the jury; and
>
> (3) the connection between the proffered scientific research or test result and the particular factual issues in the case. *Id.*

2) Four prong *Brown, Brady* test.

In the case of *State v. Schimpf*, 782 S.W.2d 186 (Tenn. Cr.App. 1989), Justice Birch reversed the admission of expert testimony concerning child sexual abuse syndrome. He commented on how most jurisdictions have stringent requirements for admitting scientific evidence. The apparent objectivity that scientific evidence bears can create an unfair disadvantage to the opposing party. *Schimpf*, 782 S.W.2d at 186. He used the test in *State v. Williams*, 657 S.W.2d 405 (Tenn. 1983) that adopted the four prong threshold test as expressed in the federal cases *United States v. Brown*, 557 F.2d 541 (6th Cir. 1977) and *United States v. Brady*, 595 F.2d 359 (6th Cir. 1979). [(Note that *Williams* was decided in 1983 and that *Johnson* was decided in 1986)].

> (1) The witness must be an expert;
>
> (2) the subject matter of the witness' testimony must be proper; "Proper"—the evidence must address the proper issue; the jury must need assistance to resolve that issue; and the evidence must substantially assist the jury in its resolution of that issue.

(3) the subject matter must conform to a generally-accepted explanatory theory; and

(4) the probative value of the witness' testimony must outweigh its prejudicial effect. *Id.* at 191.

The court explained that the modern trend expressed in the Federal Rules of Evidence goes away from the *Frye* test and it was unnecessary to use the sole test because the third prong of the *Williams* test represented the Tennessee equivalent of the *Frye* test. *Id.* at 194.

3) *Frye or Tenn. R. Evid. 702 and 703*

In *State v. Harris*, 866 S.W.2d 583 (Tn. Crim. App. 1992), an aggravated rape case, the court held that DNA forensic analysis evidence was admissible. Judge Peay stated there is a disagreement as to the proper standard of admissibility in Tennessee for scientific evidence and expert testimony. *Harris,* 866 S.W.2d at 586. The court acknowledged there were two court interpretations of the admissibility standard. The first is the *Frye* test, citing *State v. Johnson* and secondly, Tenn.R.Evid. 702 and 703, that allegedly supersede *Frye*. The *Harris* court determined the evidence presented was admissible under either *Frye* or Tenn.R.Evid. 702 and 703.

(4) Four test analysis

Judge Birch revisited the issue of scientific evidence admissibility in *State v. Myers,* supra. *Myers* was a rape case in which the defendant appealed the admission of DNA test results and the testimony of an FBI DNA expert. The *Myers* court bluntly stated that there has been no uniform application of one standard to the admissibility of expert testimony and scientific evidence. *Myers,* WL 297626 at 2. The various tests were listed as the following: (1) *Frye* test, (2) Tenn.R.Evid. 702 and 703, (3) the four prong test set forth in *United States v. Brown,* supra, and (4) the scientifically acceptable and

accurate for its purpose standard in the *Crawley* and *Pruitt* cases. The *Myers* court acknowledged that no single standard has been consistently applied to DNA evidence in Tennessee. *Id.* Instead, the analysis established that the DNA test evidence was admissible under all four of the standards.

Daubert *mention*

Two recent unreported cases casually mention the *Daubert* test. In *State v. Smith*, 03C019312CR00398 WL 361851, (Tenn. Cr. App. July 11, 1994), the court upheld the exclusion of a urine test which indicated the presence of cocaine metabolites. The urine test was found to be unreliable and in a footnote, the court cited *Daubert* as the standard used. There was no discussion of this or any other standard. In *Bishop v. Smith & Richard, Inc.*, 01A01-9405-CV-00108, LEXIS 148, (Tenn. App., March 10, 1995), a civil case, the Court of Appeals used the *Daubert* standard as the criterion of validity and relevance to assess expert evidence in a motion for summary judgment. Again, there was no mention of any analysis of this standard or any other.

Conclusion

The divergent application of the four tests parallels the struggle in the federal courts. They as we could not rely on a single standard, "general acceptance in the scientific community." In fact, it mimes what *Frye* had tried to quantify

> Just when a scientific principle or discovery crosses the experimental and demonstrable stages is difficult to define. *Frye*, 293 F. at 1014.

Our rules 702 and 703 are broader than this one standard. To end the analysis at *Frye*, because of the commission's comment to Tenn. R. Evid. 702 and 703 simply does not reflect the Tennessee case law since 1986. Even *State v.*

Johnson, as cited in the comment to Tenn. R. Evid. does not embrace the *Frye* test.

However, all these courts as well as this court are attempting to achieve one goal. The court must act as gatekeeper under Tenn. R. Evid. 104(a) to determine whether this evidence will substantially assist the jury and whether it is trustworthy. In terms of *Daubert*, that is "reliable" and "relevant." It is not so much that *Daubert* and *Daubert II* changed the federal or state standards, but that they presented a template which can be used in any situation and is not fact specific. This template gives an analysis to a trial judge to determine if the evidence measures up. Is it good science, which is reliable and relevant, so that the jury is not misled by unfamiliar scientific evidence.

Therefore, as an aid to assist the court, the court will use the analysis in *Daubert* and *Daubert II*, keeping in mind the differences between the Federal and Tennessee Rules of Evidence.

IV. *Evidence in CSX cases*

The court heard testimony in this case from seven experts over a period of four days and will consider, based upon Tenn. R. Evid. 104(a), 702, 703 and generally on the criteria of *Daubert* and *Daubert II*, whether each expert witness would be allowed to testify if called to the stand during a trial. The inquiry in this case is a two-pronged one. 1) Can expert testimony show the connection between workers who have long-term exposure to organic solvents at low doses and medical conditions that result from such exposure?, i.e., reliability and relevance. 2) Can the experts show causation between organic solvents and the particular complaints of the each plaintiff?

Plaintiff's Experts

Dr. Edward Baker: Dr. Baker is an M.D., board certified in Internal Medicine and Occupational Medicine and

an M.P.H. and a Master of Science from the Harvard School of Public Health with an emphasis in occupational health. He has held numerous positions with the Harvard School of Public Health, later with the National Institute of Occupational Safety and Health and finally with the Public Health Practice Program Office at the Center for Disease Control. He is a fellow in the American College of Epidemiology, and received the Authorship Award at the American College of Occupational Medicine in 1989. Dr. Baker has written 26 articles for peer-reviewed journals and four book chapters for textbooks, all on the subject of the effects of exposure to solvents. He was the only United States Representative to the WHO Conference in Denmark in 1985 and also to the conference at Duke University. The WHO Conference concluded:

> Clinical, epidemiological and experimental data indicate that long-term occupational exposure to organic solvents may cause adverse effects in the central and the peripheral nervous systems.

They developed categories:

> organic affective syndrome
> mild chronic toxic encephalopathy
> severe chronic toxic encephalopathy (at TAB 13, Exhibit 11)

Further, he was a representative to a European Conference in 1990 and in Singapore in 1992. The Duke conference in 1985 assumed the causative connection but concentrated on defining the levels of the symptoms and whether removal from the solvents would reverse the symptoms.

Dr. Baker did a number of epidemiological studies on various groups of exposed painters. However, for the court's purposes, one of the most helpful articles is "A Review of Recent Research on Health Effects of Human Occupational Exposure to Organic Solvents." in the *Jour-*

nal of Occupational Medicine, Vol 36, No. 10 (October 1994), [at TAB BAKER 1994, Exhibit 63]. In this article he summarizes the findings of the major studies since 1985. [Although he does not use the famous Gade study, "Chronic painter's syndrome. A reanalysis of psychological test data in a group of diagnosed cases, based on comparisons with match controls." *Acta Neurol.Scand* 1988, he does mention its significance, but discounts it somewhat.] He summarizes the findings of 13 studies and 5 follow-up studies. From these studies he concluded that "these cross-sectional studies, viewed in the aggregate, support the view that chronic solvent exposure causes impairment of neurobehavioral function." (p. 1082) He further found that dose-response was very important. He found that in "currently employed workers, if they work where exposures are controlled below the permissible exposure limits," then there is little evidence of chronic encephalopathy. However, he found studies showed exposure over 10 years increased the risk, particularly if the exposure exceeded NIOSH standards.

Dr. Baker was questioned at length. Defendant's experts criticized Dr. Baker's studies and other studies as being "epidemiologically incorrect." They further criticized him for unaccounted confounders, for insufficient attention paid to original I.Q. scores and alcohol abuse. The defendant's primary complaint was the insufficiency of anecdotal evidence of solvent exposure. Dr. Baker said clearly that for exposure to qualify as critically dangerous it had to be above the prescribed limits of exposure, meaning that a worker had to experience acute exposure several times per day over a period of time, probably at least over 10 years. He defined acute exposure as that exposure which would cause a person to take a break and get a breath of fresh air outside several times per day. He testified that if another expert, such as Dr. Kelly, testified that exposure to Trichlorethane at levels of 50-75 ppm would cause chronic encephalapathy, that expert would be out of the mainstream.

In his article, Dr. Baker was clear that his objective was prevention. Dr. Baker detailed what should be done for prevention strategies, such as substituting water-based paints for solvent-based paints, being more selective in choosing persons who work in a solvent-exposed position —avoiding persons with asthma, peripheral neuropathy, skin disorders, testing for cognitive deficits, avoiding persons with heavy alcohol consumption. He testified that such prevention was also the objective of the National Institute for Occupational Safety and Health Centers for disease Control (NIOSH). In 1987, they issued a bulletin stating:

> Epidemiological studies have also shown statistically significant increases in neurobehavioral effects in workers chronically exposed to organic solvents. These effects include disorders, characterized by reversible subjective symptoms (fatigueability, irritability, and memory impairment), 'sustained' changes in personality, mood (emotional instability and diminished impulse control and motivation), and impaired intellectual function (decreased concentration ability, memory and learning ability. (TAB 15, P.1, Exhibit 11)

Dr. Baker finally discussed that this subject was extensively discussed in three medical textbooks:

> *Textbook of Clinical Occupational and Environmental Medicine.* Rosenstock (1994)
>
> *Environmental and Occupational Medicine,* ROM (1992)
>
> *Solvent Neurotoxicity,* Arlien-Soberg (1991).

The authors all agreed there was a causative link between chronic encephalopathy and long term low dose exposure to solvents. The points of disagreement were how common, how prevalent and how long lasting.

Under *Daubert* the analysis of Dr. Baker's testimony is as follows:

1) Is it testable? The epidemiological studies cited by Dr. Baker show that his theory is testable under various exposures to long-term solvent use. There is still a question as to the exact dose/response of certain chemical or combinations.

2) Has it been subjected to peer review? There is no question that this theory has been discussed in peer reviewed articles, in this country and internationally.

3) Is there a known or potential rate of error? There are criticisms of some studies that do not control sufficiently for confounders. However, the rate of error is usually accounted for in the studies. There no single general flaw.

4) Is there "general acceptance?" According to Dr. Baker there is a general acceptance in the occupational health community. The court is mindful that another similarly situated judge, Judge Michael Weatherby of Duval County, Florida, considered some of the same evidence based on the same studies under the *Frye* test standard. He found there was no "general acceptance." This court respectfully disagrees with his analysis. If this factor is not the only controlling factor, the additional factors support this court's analysis that the proposed experts may testify.

5) Was thhe testimony developed solely for the litigation? Dr. Baker had never even spoken to an attorney until one and one-half years ago. His objective was research and prevention.

6) Is the subject too new for peer reviewed articles? No, this subject has been studied since the early 1900's.

Dr. Baker will be allowed to testify in Second Circuit Court on these issues.

Dr. Douglas Linz:

Dr. Linz testified by deposition. He is an M.D. with an emphasis in Occupational Medicine. He is currently an Associate Professor of Environmental Health and Director of Occupational Medicine at the University of Cincinnati Medical Center. Previously he was the director of the University of Cincinnati Occupational Medicine Training Course for Physicians. He has written four articles on the subject since 1985. He currently sees patients in his clinical program for chronic encephalopathy. He is presently involved in a study of 186 CSX workers who are apparently in the Ohio area. He is working with various other scientists to assemble the data to follow the proper epidemiological study model. He testified about how he goes about diagnosing a worker who is presented with neurological and depression complaints. It is essentially a differential diagnosis model, just like any other physician. He rules out other factors which may have some impact on the patient. He sends appropriate patients for neuropsychological testing. He also has a postural sway test, which is a newer test to measure neurological deficit.

Dr. Linz has concluded per the studies that are available to all the occupational physicians that chronic low dose exposure to solvents can cause chronic encephalopathy.

On cross-examination he was asked about his relationship with Dr. Michael Kelly. He stated that he has studied with Dr. Kelly for a short time. Although he respects Dr. Kelly he believes that Dr. Kelly will diagnose a worker with solvent induced encephalopathy more often than other doctors will. Although he is either directly or indirectly involved in some litigation processes, his opinions were formed long before he got involved in any litigation.

Dr. Linz's testimony meets all the criteria of *Daubert* and Tenn. R. Evid. 702 and 703. He will be allowed to

testify in Second Circuit Court on these matters. He could potentially testify about the second prong of the inquiry—can the exposure be directly linked to a specific plaintiff.

Dr. Michael Kelly: Dr. Kelly is an M.D., board certified in Internal Medicine and Preventive Medicine/Occupational Medicine. He is presently employed as a Medical Director of Occupational Health Services and Chief of Internal Medicine at the St. Lawrence Work and Health Institute at St. Lawrence Hospital in Lansing, Michigan. He has been primarily involved in clinical practice or teaching during his entire career. He is a member of the Society for Occupational and Environmental Health as well as other societies. He has written a number of articles, but none on this subject.

Dr. Kelly has seen all the 82 CSX workers in these cases so far. The court presumes that he has made a diagnosis of chronic toxic encephalopathy caused by organic solvents in each one of the cases. Before the Court in this case, he testified about just one person in the sample, Michael Brady. He diagnosed him with organic affective syndrome with depression, based upon a long history of exposure to neurotoxins. He sent the workers to Dr. Gary Solomon of Nashville, a neuropsychologist for neuropsychological testing. [Dr. Linz testified that Dr. Solomon apparently did a credible job in his reporting.] He found his I.Q. subaverage, although his work and education history indicated a higher I.Q. His short term verbal memory was almost three standard deviations below norm. He was depressed and had low average manual speed and dexterity. He described the method of diagnosis of each worker, generally called a differential diagnosis. He was of course aware of the literature about exposure to solvents. Occupational health is his speciality. He was cross-examined at length about whether he had a predisposition to diagnose these workers. He was further cross-examined about his own views about solvent ex-

posure at very low levels [25ppm as opposed to the norm of 350ppm for one of the solvents.] Regarding Mr. Brady, Dr. Kelly was questioned about other confounders such as prior accidents and separation from his wife. Dr. Kelly is clearly the evaluating physician here and carries with him the cloak that all physicians carry with him who are in his position. He may have a bias. He may very well, as Dr. Linz stated, find this diagnosis quicker than other physicians do. Nonetheless, as Justice Blackmun stated in *Daubert*. This is not a

> 'free-for all' in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions. . . . Vigorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate means of attaching shaky but admissible evidence." (p. 2798) *Daubert*, 113 S.Ct. at 2798.

Blackmun added there is always a directed verdict. That is true in this case.

We have yet to develop exactly what the dose of exposure is for each worker, how long they were exposed at what levels, what effect their family problems have on them, what their record in school was at an earlier age, what financial problems they might have, etc. That is all under the subject of the initial presentation and "vigorous cross-examination."

Dr. Kelly will be given the opportunity to testify, just as any physician will testify about his diagnosis, based upon the relevant literature; however, he will not be allowed to testify as to his own opinion on the possible effects of low dose exposure in less than the amounts that have been tested for in other studies or that are set by the various monitoring organizations, until there is scientific evidence to support that fact.

Dr. Kelly has met the criteria of *Daubert* and Tenn. R. Evid. 702 and 703. He follows normal diagnosis proce-

dures with the additional assistance of a neuropsychologist. The literature he uses to consider his diagnosis has been peer reviewed and "generally accepted" in the occupational health scientific world. He is a pre-eminent expert. He has had clinical experience. His weakness as an expert is that he did not see these patients in any other setting than in litigation and does not continue to treat them. That weakness primarily goes to the weight and not the substance of the diagnosis.

Dr. Frumpkin's Testimony:

Dr. Frumpkin is an M.D. with an M.A. in Public Health and Occupational Health and an emphasis in epidemiology. He is presently a professor in the Occupational Health department of Emory University Medical School. In his clinical practice he has seen CSX employees who have been exposed to TCA and 1,1,1,. He has made chronic toxic encephalopathy diagnoses in his clinical practice. He has written numerous articles on various subjects as well as textbook chapters but no articles on this specific subject. Nonetheless, he was thoroughly familiar with the subject matter prior to his retention as an expert. He is president of the Association of Occupational and Environmental Clinics and is on the editorial board of *Industrial Medicine*. In other words, he is the person who decides whether other scientists' opinions are contained in one of the important journals in his field. There is no question that he is a preeminent expert in his field.

His opinion is that the diagnosis of chronic encephalopathy as a causative factor of low dose exposure to organic solvents is generally accepted in the world and the U.S. He was surprised that it was necessary to have such a hearing to test this diagnosis. When asked how he formed his opinion as to causation, he stated that it is best to review all the studies, pay the most attention to the best studies and pay least attention to the worst studies

and then follow the best studies. He explained that the reason that the summaries in many studies discuss further research is that researchers like to research and there are unanswered questions. How long is the exposure? What levels of exposure are there? What levels are safe?

Prior to the August hearing, he had never appeared as an expert in a court proceeding. He discussed six representative studies, pointing out the approved epidemiological formula for a good study, the theory of confounders, controlling bias, using control groups, studying exposed and non-exposed groups of workers. He discussed in detail what was good and bad about each study, supporting his initial conclusion.

Dr. Frumpkin's testimony fits the criteria for *Daubert* and in Tenn. R. Evid. 702 and 703. If he was called as a witness in Second Circuit Court, he clearly would be allowed to testify.

Defendant's Experts:

Dr. Edelman has a Ph.D from Harvard, Wellesley and is board certified in Toxicology and Occupational and Environmental Medicine. He is currently a professor at Vanderbilt Medical School. He is a member of the American Academy of Clinical Toxicology and the American Association of the Advancement of Science. He discussed the field of toxicology. All substances are toxic, but the differences are in the amount. The dose/response is at the heart of all toxicological studies. Dr. Edelman was primarily concerned about the specific kinds of chemicals in the solvents discussed. He said that it was very difficult to analyze the dose/response of the solvents, since each chemical was different. He suggested that it would be important to measure the workplaces for exposure to really find out how much specific chemicals were in the air.

When asked if the low dose exposure theory was accepted in the "medical community," he said that most had never heard of it. Toxicologists did not accept the theory, since there was just some association between unspecified exposure and self-reported symptoms. He thought that occupational medicine doctors did accept the theory at some solvent level at some dose, but there was no commonality as to specific agents. He criticized the studies because there were insufficient controls for confounders. He particularly criticized the Bleeker study and the Hanninen studies as not being "good science."

On cross-examination he testified that he had often served as an expert witness, testifying at least 100 times. However, he had never written on these types of cases or testified on the subject prior to this specific litigation.

Since Dr. Edelman is clearly an expert in his field of toxicology, obviously knowledgeable about dose/response relationship between exposure to solvents and toxic encephalopathy, he would clearly be allowed to testify under *Daubert* and Tenn. R. Evid. 702 and 703. He clearly holds another opinion to the plaintiff's experts, but that does not make him ineligible to testify. It just makes a lawsuit.

Dr. McLaughlin, is a Ph.D in Epidemiology from the University of Minnesota. He is presently president of the International Epidemiology Institute, Ltd. in Rockville, Maryland, a private institute. He has been with the National Cancer Institute since 1983. He is a member of the American Epidemiological Society and Fellow of the American College of Epidemiology. He has written 168 articles in peer-reviewed magazines, including one that associates reduced risk of esophageal cancer with 3-4 cups of green tea per day. His area of emphasis is the epidemiology of renal cancer, occupational epidemiology and risk assessment. He testified at length about the hierarchy of epidemiological studies, starting from case re-

ports to randomized trials, to cross-sectional design, to case-control studies to cohort studies.

Dr. McLaughlin testified that he had never read anything in this field before he formed his opinion in the two weeks before the deposition on August 11. He was a bit surprised to know that he had "already formed an opinion" in Rule 26 Interrogatory Answers before he had read the studies where he stated

> "It is not generally accepted that chronic low-dose exposure to solvents such as TCA, TCE (1, 1, 1) Perc or mineral spirits will cause permanent brain or central nervous system damage in individuals so exposed without episodes of hypoxia or anoxia."

His primary criticisms were that the studies had a general lack of a control group and there was a lack of adjustment for age, education, alcohol use and abuse, and IQ. He found that the negative studies were better designed methodologically, particularly the study done by Ann Spurgeon. [In that study, she found that there was no association between workers who were exposed to below governmental limits exposure to solvents and toxic encephalopathy.] In general the field is not "epidemiological sophisticated," such as the cancer field. He finds that it is necessary to conduct methodological studies from various countries to show a causal connection. He contends that presently the causal connection is only a hypothesis. He finally agreed that solvents will cause deleterious effects and urotoxic problems. The controversy will center on what is the lowest level of risk.

Dr. McLaughlin's testimony fits the criteria of *Daubert* and Tenn. R. Evid. 702 and 703. He is a bit suspect as he was unfamiliar with this field prior to the litigation. The court will find him qualified to testify as an expert in the field of epidemiology.

Dr. Robert James is a Ph.D in Pharmacology and post Doctoral Fellow in Clinical Pharmacology from Vander-

bilt. Presently he is Associate Scientist in the Center for Environmental and Human Toxicology at the University of Florida. He is also President/Toxicologist of TERRA, Inc., a private institution. He has written 55 articles for peer-reviewed journals. Prior to his involvement since the spring of 1995, he had never read any articles in this field before. He has testified as an expert several times in other cases, but not on this subject.

In preparation for his testimony, Dr. James studied 45 cross-sectional studies and rated them positive, negative, and uninformative. He found that on this list of criteria, 84% supported the hypothesis, while 16% did not support hypothesis. His primary criticism was the way in which the studies were performed. He found that most of the studies did not control for confounders, particularly the pre-morbid IQ, and did not use proper matching in the studies. His overall opinion was that this "hypothesis" was not generally accepted in the toxicology medical community.

Dr. James' testimony was helpful in discussing the various types of epidemiological studies. Dr. James' zeal for study bashing was remarkable, given his short time with the subject matter. He was absolutely convinced most studies were negative or uninformative, even if the conclusions appeared to be positive.

The court is a bit suspect of an expert who is not in the field of occupational health or epidemiology and had no prior experience. However he has a right to criticize the studies, develop his own summaries and testify about his opinions. He will be allowed to testify pursuant to *Daubert* and Tenn. R. Evid. 702 and 703.

V. Conclusion

The court has spent a lot of time in this case reviewing the studies presented by the various parties as well as looking behind the scenes at some of the other cases which

led up to the *Daubert* decision and its progeny. In all the decisions about the association between Bendectin and birth defects, there was a veritable dearth of epidemiological studies that connected the drug and the birth defects. In fact, all the evidence weighed in on the other side of the equation, whether you considered the evidence by the looser standard of *Daubert* or under the more restrictive standard of *Frye*. There was a real desire on behalf of the courts resolving Bendectin cases to consider the connection between the drug and birth defects, since the results were so tragic. The cases received a lot of publicity. As a result the drug company took the drug off the market, or at least physicians no longer prescribed the drug to their pregnant patients. The bottom line, however, was that there was simply no significant standard deviation from the norm in those studies.

This somewhat surprising conclusion was also reached in the Agent Orange cases. *In re: "Agent Orange" Product Liability Litigation*, 611 F.Supp. 1223 (D.C.N.Y. 1985). Prior to this decision, Judge Weinstein had presided over a huge class action settlement for Vietnam veterans and members of their families in Multi District Litigation. In other words, the government had paid millions of dollars to those veterans who were exposed to the Agent Orange compound. Some 600,000 persons had been exposed to Agent Orange, including family members. This court decision pertained only to 281 plaintiffs, the remaining were opt-out persons. The court found that there was no causal link between Agent Orange and their maladies, pursuant to at least 35 studies. The totality of the plaintiffs' cases rested upon hearsay checklists that the doctors had devised. The physicians had never personally examined the plaintiffs. The court rejected the claims of the plaintiffs stating:

> "the unreasonableness of Dr. Singer's affidavits is so blatant that a hearing would be useless. The court takes judicial notice—based on hundreds of trials—

> that no reputable physician relies on hearsay checklists by litigants to reach a conclusion with respect to the cause of their afflictions." "*Agent Orange" Product Liability*, 611 F. Supp. at 1246.

There are presently pending thousands of breast implant cases in both federal and state courts. For about one year, we have been struggling to implement a 4.8 billion dollar settlement, which is now confused by a bankruptcy filing. There are many studies on both sides of the issue. Dr. McLaughlin stated unequivocally there are no studies that show a causative effect between silicone and unspecified autoimmune diseases. This type of hearing may be oft repeated.

The court raises the history of these three major cases for one reason—to contrast them with the case at issue. In this case, it is clear that there are studies that support the causative factor and studies that do not, based upon a different dose-response. However, this is an entirely different issue than that raised by the three aforementioned groups of plaintiffs. First of all, the chemical itself is a toxic substance which causes acute effects, or anoxia in a high dose. Secondly, it has been the focus of international conferences, two in 1985 and 1990 and 1992. The conclusions at those conferences was that there was a definite link between long-term solvent exposure and chronic toxic encephalopathy. The questions raised were whether those effects were reversible and how the situation could be remedied. The latest studies acknowledge that the dosage exposure of the workers may be less than it was 20 years earlier. The focus of all these studies has not been litigation, but on preventive measures. Medical textbooks also present the causative factor as a truism. The only question is the "prevalence" and excessive dosage." This is not "junk science." It is grounded in scientific theory. It is generally accepted in the occupational health community.

There are clearly questions raised in this lawsuit, which are far from being answered. The initial question is

whether the exposure to certain chemicals at CSX can cause problems in its workers. If there are no measurements at the facility over the years, there will have to be anecdotal evidence of workers to establish their acute reactions to the chemicals, and their individual exposure to the chemicals. The secondary question is can Dr. Baker or Dr. Solomon or Dr. Linz clearly establish that any one of these persons has chronic toxic encephalopathy, from any source? Since the preliminary question has been determined, that is a matter for the jury to decide. More than likely, these claimants will be examined by a physician chosen by the defendant. He or she will likely testify that the claimant's symptoms are not related to chronic toxic encephalopathy. That is a situation that happens every day in courts across America—competing experts. The only difference in this case is the controversy raised over the causation issue of the solvents. Finally, there is the question, if the above two questions can be answered affirmatively, how are the workers ultimately affected when they are no longer exposed to the solvents? Do they have permanent damages? How does loss of memory or depression actually affect their lives? We still have a major lawsuit here. It is time to get on with it.

A simultaneous order shall be issued with this Opinion.

Entered this 3rd day of October, 1995.

/s/ Marietta M. Shipley
JUDGE MARIETTA M. SHIPLEY

IN THE SECOND CIRCUIT COURT
FOR DAVIDSON COUNTY, TENNESSEE

Case No. 93C-2215
All Consolidated Cases

KENNETH MCDANIEL,
Plaintiff,

vs.

CSX TRANSPORTATION, INC.,
Defendant.

ORDER

It is hereby ordered that the Memorandum Opinion entered simultaneously in this case represents the order of the court in this matter.

Entered October 3, 1995.

/s/ Marietta M. Shipley
JUDGE MARIETTA M. SHIPLEY

APPENDIX D

IN THE SUPREME COURT OF TENNESSEE
AT NASHVILLE

Filed: December 8, 1997

Davidson Circuit
No. 01S01-9605-CV-00095

KENNETH MCDANIEL,
Plaintiff/Appellee,

VS.

CSX TRANSPORTATION, INC.,
Defendant/Appellant.

ORDER ON PETITION FOR REHEARING

The defendant has filed a petition for rehearing of this appeal pursuant to Tenn. R. App. P. 39. We have considered all of the arguments raised in the petition and have found them to be without merit.

Accordingly, it is ORDERED that the petition for rehearing is denied.

PER CURIAM